

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Psychopharmacological Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Psychopharmacological Drugs Advisory Committee

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on July 19, 2000, 8 a.m. to 5 p.m.

Location: Holiday Inn, Versailles Ballrooms I, II, and III, 8120 Wisconsin Ave., Bethesda, MD.

Contact Person: Sandra L. Titus or LaNise S. Giles, Center for Drug Evaluation and Research (HFD-21), 5600 Fishers Lane (for express delivery, 5630 Fishers Lane, Rm. 1093) Rockville, MD 20857, 301-827-7001, or e-mail Tituss@cder.fda.gov, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area) code 12544. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will consider the safety and efficacy of new drug application (NDA) 20–825, ZeldoxTM (ziprasidone hydrochloride capsules, Pfizer, Inc.), proposed for the management of psychotic disorders.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by July 17, 2000. Oral presentations from the public will be scheduled on July 19, 2000, between

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approximately 1 p.m. to 2 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before July 17, 2000, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app.

2).

Senior Associate Commissioner.

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